UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 25, 2007

MEMORANDUM

SUBJECT: Review of "Determination of Transfer of Pyrethrin (PY) and Piperonyl Butoxide (PBO) Residues to the Hands from a Discharged Indoor Fogger Aerosol Canister and the Paper Placed Under the Aerosol Canister" (MRID 46188622) D336765.

FROM: Matthew Lloyd, Industrial Hygienist
Reregistration Branch 1
Health Effects Division (7509P)

THROUGH: Jeff Evans, Biologist
Chemistry and Exposure Branch
Health Effects Division (7509P)

TO: Cathryn O'Connell
Reregistration Branch 2
Special Review and Reregistration Division (SRRD) (7508P)

Attached is a review of a study conducted to determine the transfer of Pyrethrin (PY) and piperonyl butoxide (PBO) residues to the hands from the application of an indoor aerosol fogger. The study was submitted by the Pyrethrin, Piperonyl Butoxide, MGK-264, Deltamethrin, Non-Dietary Exposure Task Force. A primary review of this study was conducted by Versar, Inc. under the guidance of HED (see Attachment). The following is a summary of the study and its findings.

Study Design and Sampling

X5295-98 (a total release aerosol fogger product), containing 0.505% ai pyrethrin and 1.00% ai piperonyl butoxide, was applied per label instructions as a total release fogger in the center of two 16 ft. x 16 ft. x 8 ft. test rooms (Simulated Residential Rooms). Eight separate runs were performed using two test rooms over the course of four days. Four pages of a newspaper were stacked on top of each other and placed underneath the aerosol can before it's release.

The ventilation systems in the Simulated Residential Rooms (SRRs) were turned off during application and for three hours after application. The dampers in the rooms were opened for 30 minutes after application. After the 30 minute ventilation period, the test subjects entered the room and removed and disposed of the used aerosol can and newspaper. Study personnel measured residues transferred to the hands of study participants using an isopropyl alcohol based, double wipe method.

Results

Results were reported for both PYI, PBO, and PY, a total PY value calculated from the PYI data using a conversion factor derived from the percentages of total PY and PYI in the formulated product.

Total Transfer:

Total PY and PBO transfer residues from the canister and newspaper together ranged from 0.024 to 0.173 $\mu g/cm^2$ and from 0.035 to 0.307 $\mu g/cm^2$, respectively.

Transfer to Non-Dominant Hand:

The PY and PBO residues transferred from both the newspaper and the empty canister to the non-dominant bare hands ranged from 0.024 to 0.068 $\mu g/cm^2$ and from 0.035 to 0.143 $\mu g/cm^2$, respectively. The PY and PBO mean residues, transferred to the non-dominant bare hands were 0.043 ± 0.015 $\mu g/cm^2$ and 0.078 ± 0.034 $\mu g/cm^2$ respectively.

Transfer to Dominant Hand:

The PY and PBO residues transferred from both the newspaper and the empty canister to the dominant bare hands ranged from 0.027 to 0.173 $\mu g/cm^2$ and from 0.049 to 0.307 $\mu g/cm^2$, respectively. The PY and PBO mean residues, transferred to the non-dominant bare hands were 0.105 ± 0.052 $\mu g/cm^2$ and 0.185 ± 0.086 $\mu g/cm^2$, respectively.

Data was not corrected, as all field fortifications were above 90%. Results from the study indicate that the dominant hand residue is over twice the non-dominant hand residue. The ratio of PBO to PY on the hand is close to 2, approximately the ratio of those two compounds in the product formulation.

The primary review identified limitations of the study that do not explicitly meet EPA Guidelines under OPPTS Series 875; however, HED does not believe these limitations impair the utility of the study.

Conclusion

The requirements for this study were specified by the U.S. Environmental Protection Agency's (U.S. EPA) OPPT Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines. The relevant guidelines and the protocol provided along with the study were used to review the study. Overall, the majority of the procedures performed and the quality of the data generated in this study conformed to the criteria set for the in the protocol and guidelines. The data are of sufficient scientific quality to be used to determine exposure.

Currently, there is no portion of HED's Residential Exposure Assessment SOPs that address post application dermal exposure to total release aerosol foggers. The data generated from this Study Report may be revisited for utility should the SOPs be revised to include a post application dermal exposure assessment for total release foggers.

Versar inc.

MEMORANDUM

TO:	Margarita Collantes	cc:	110082.4000.001.01
FROM:	Teri Schaeffer /Linda Phillips		
DATE:	March 24, 2004		
SUBJECT:	Review of "*Determination of Transfer of Pyrethrin (PY) and Piperonyl Butoxide (PBO) Residues to the Hands from a Discharged Indoor Fogger Aerosol Canister and the Paper Placed Under the Aerosol Canister*" (Project #: 01-027-PY01)		

This report reviews a study entitled "*Determination of Transfer of Pyrethrin (PY) and Piperonyl Butoxide (PBO) Residues to the Hands from a Discharged Indoor Fogger Aerosol Canister and the Paper Placed Under the Aerosol Canister.*" The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study.

Reviewers: Teri Schaeffer /Linda Phillips **Date: March 24, 2004**

STUDY TYPE: Active Transfer; Hands

TEST MATERIAL: The formulated test substance was a prototype total release indoor aerosol fogger containing 0.505% pyrethrin (CAS no. 8003-34-7) and 1.00% piperonyl butoxide (CAS no. 51-03-6) as the active ingredients. The formulation was typical of the currently marketed formulations developed by the McLaughlin Gormley King Company (MGK) used for indoor fogging.

SYNONYMS: Pyrethrin (PY) and Piperonyl Butoxide (PBO)

CITATION:

Author/Study Director:	Sami Selim, Ph.D.
Title:	*Determination of Transfer of Pyrethrin (PY) and Piperonyl Butoxide (PBO) Residues to the Hands from a Discharged Indoor Fogger Aerosol Canister and the Paper Placed Under the Aerosol Canister*
Report Date:	October 28, 2002
Testing Facility:	Toxcon Health Sciences Research Centre, Inc. 9607 - 41 Avenue Edmonton, Alberta Canada T6E 5X7
Analytical Facility:	Enviro-Test Laboratories/XENOS Division Unit 13 - 210 Colonnade Road Nepean, Ontario Canada K2E 7L5
Identifying Codes:	Toxcon Study No.: 01-027-PY01 Xenos Project No.: XEN02-26

SPONSOR: Non-Dietary Exposure Task Force

EXECUTIVE SUMMARY:

This report reviews "*Determination of Transfer of Pyrethrin (PY) and Piperonyl Butoxide (PBO) Residues to the Hands from a Discharged Indoor Fogger Aerosol Canister and the Paper Placed Under the Aerosol Canister*." The purpose of the study was to determine the amount of pyrethrin (PY) and piperonyl butoxide (PBO) residues that are transferred to the hands of subjects in the process of discarding an empty aerosol canister that contained 0.505% PY and 1.00% PBO as the active ingredients, and the paper placed under it.

Eight subjects participated in the study. Eight separate runs were performed using two test rooms on four separate days. Aerosol canisters were placed on newspapers in the middle of the test rooms. The ventilation system of the test rooms was turned off and the aerosol cans were activated. The rooms were closed up for three hours and then ventilated for 30 minutes prior to initiating the hand transfer phase of the study. Each subject removed the empty canister with the dominant hand, placed it in a plastic bag and then crumpled the newspaper which was under the canister using both hands. Afterwards the subjects had their hands wiped separately with two dressing sponges wetted with isopropyl alcohol (IPA).

Total hand residues were calculated by the study author for each hand of the test subjects. Residues are reported for PYI , PY, and PBO. Versar's calculated total PY and PBO transfer residues from both the canister and newspaper ranged from 0.024 to 0.173 µg/cm^2 and from 0.035 to 0.307 µg/cm^2, respectively. Versar calculated PY and PBO

residues transferred from the newspaper to the non-dominant bare hands which ranged from 0.024 to 0.068 µg/cm^2 and from 0.035 to 0.143 µg/cm^2, respectively. The PY and PBO residues transferred from both the newspaper and the empty canister to the dominant bare hands ranged from 0.027 to 0.173 µg/cm^2 and from 0.049 to 0.307 µg/cm^2, respectively. Versar did not have to correct the data, as all field fortification recoveries were >90%. The results from this study indicate that the dominant hand residue is over twice the non-dominant hand residue. The ratio of PBO to PY on the hand is close to 2, which is the ratio of the compounds in the formulation.

The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study. Overall, the majority of the procedures performed and the quality of the data generated in this study conformed to the criteria set forth in the protocol and guidelines. However, certain issues of concern were noted:

$ A label was not provided for the test product; therefore, it is unclear whether the rate is appropriate for the intended use.

$ None of the test conditions (temperature, barometric pressure, ventilation) were reported.

$ According to the Study Report, the fogger canister was placed in a plastic bag and weighed before and after release of its contents to determine the actual amount of formulation that was delivered to the test room taking into account the weight of the bag. However the results from this were not discussed. The actual amount of formulation delivered to the test room was not reported.

COMPLIANCE:
A signed and dated Data Confidentiality statement was provided. A signed and dated GLP Compliance Statement was provided. It was noted that this study was performed according to the US EPA FIFRA Good Laboratory Practice Regulations currently in effect (40 CFR, Part 160). However, scanning of the hand palmer surfaces and information recorded on subject entry and exit was not done according to GLP Regulations. A Quality Assurance statement was provided.

GUIDELINE OR PROTOCOL FOLLOWED:
The study was reviewed using OPPTS Test Guidelines Series 875, Occupational and Residential Exposure Test Guidelines, Group B: 875.2300. The study was conducted following Xenos and Toxcon Standard Operating Procedures and the protocol of the Non-Dietary Exposure Task Force (Toxcon Protocol No. 01-027-PY01).

I. MATERIALS AND METHODS

A. Materials:

1. Test Material:

Formulation:	X5295-98 is a total release fogger in an aerosol canister developed by McLaughlin Gormley King Company (MGK). The fogger used in the experiment contained pyrethrin (0.505 % ai) and piperonyl butoxide (1.00% ai) as the active ingredients.
Lot/Batch # formulation:	Batch GLP-1622 (test product); GLP-1628 (reference)
Formulation guarantee:	Certificate of Analysis provided. The Certificate of Analysis stated that the test substance contained 0.505% total pyrethrins and 1.00% PBO. The analysis was dated June 6, 2002. The Certificate of Analysis stated that the reference substance (used to fortify control samples) contained 0.76% total pyrethrins and 1.51% PBO. The analysis was dated June 20, 2002.
CAS #(s):	Pyrethrin: 8003-34-7; Piperonyl butoxide: 51-03-6

Other Relevant Information:	Toxcon ID No.: PY01 T003 for the test product and Toxcon ID No. PY01 T006 for the reference substance; MGK is the manufacturer of the test product.

2. Relevance of Test Material to Proposed Formulation(s):

Pyrethrin and piperonyl butoxide are active ingredients used in formulated consumer products intended for use in residential buildings. The product used was total release fogger formulation typical of indoor fogger formulations developed by McLaughlin Gormley King Company (MGK). The label for the test product was not provided with the study.

B. Study Design:

There were three amendments to and no deviations from the study protocol. The amendments to the protocol involved the following: (1) a decision was made to move the fortification procedure to a similar room as the rooms where the aerosol canisters were activated; (2) text in the protocol was edited to read "The opening of the aerosol can will be pointing upward"; and (3) it was decided that the test subjects would not handle the pre-labeled plastic bags in which the empty canisters were placed, in order to prevent contamination.

1. Site Description:

Test locations:	Two test rooms, referred to as simulated residential rooms, were located at the Toxcon Health Sciences Research Centre in Edmonton, Alberta, Canada. The rooms were prepared according to Toxcon SOP No. E-025: *Preparation of Test Rooms Prior to an Experiment*.
Meteorological Data:	Target test room conditions prior to application included an air exchange rate of 0.6 ± 0.1 air change per hour (ACH), a temperature of 72 ± 4^{o}F and a relative humidity of $50 \pm 10\%$.
Ventilation/Air-Filtration:	The ventilation system for the spray room was turned off during application and for three hours after the application (with dampers closed). The dampers were opened after the three hours and for a 30 minute drying period, the room conditions were adjusted to reach the conditions prior to application.

2. Surface(s) Monitored:

Room(s) Monitored:	Two test rooms, referred to as Simulated Residential Rooms (SRRs), were utilized in this study. Four pages of a newspaper were stacked on top of each other and placed in the center of the test room. An aerosol canister was placed in the center on top of the paper.
Room Size(s):	The dimensions of the test rooms within which the aerosol canisters were activated were 16 ft x 16 ft x 8 ft.
Types of Surface(s):	Hand surfaces (palms) of eight test subjects.
Surface Characteristics:	The subject's hands were washed with liquid Ivory soap, rinsed with tap water, and dried with a paper towel prior to handling the empty aerosol canister and newspaper.
Areas sprayed and sampled:	The aerosol fogger canisters were activated in test rooms, which were 16 ft x 16 ft x 8 ft. PY and PBO residues were transferred to the palms of the test subjects when they pick up and dispose of the empty canisters and newspapers. The

hand palmer surface areas of the subjects were measured using an ink image of the palm side of each hand.

Other products used: None

3. Physical State of Formulation as Applied : Fogger

4. Application Rates and Regimes:

Application Equipment: A total release aerosol fogger canister containing the formulated test product.

Application Regime: Eight separate runs were performed using two test rooms on four separate days. For each run, an aerosol canister was placed on a newspaper in the middle of the test room. The ventilation system for the test room was turned off (dampers closed) prior to the application and during the deposition period. The aerosol canister was shaken well, placed on the center of the newspaper and then activated. The room was closed for three hours and then ventilated for 30 minutes prior to initiating the hand transfer phase of the study.

Application rate(s): According to the Study Report, the application of the fogger test product was consistent with typical label instructions. The empty canister was placed in a plastic bag and weighed before and after release of its contents to determine the actual amount of formulation that was delivered to the test room taking into account the weight of the bag. However the results from this were not discussed. The actual amount of formulation delivered to the test room was not reported.

Equipment Calibration Procedures: Not applicable to this study.

Was total deposition measured? No, total deposition was not measured in this study.

D. Sampling:

Surface Areas Sampled: The palms of eight subjects were sampled using dressing sponges dampened with IPA. The range of hand palmer surface area for the left hands ranged from 57.8 cm^2 to 91.6 cm^2 with a mean of 76.4 cm^2 and for the right hands ranged from 52.5 cm^2 to 93.1 cm^2 with a mean of 75.5 cm^2.

Replicates per sampling interval: Both hands of the eight test subjects were sampled resulting in 8 dominant hand replicates and 8 non-dominant replicates.

Number of sampling intervals: There was only one sampling interval that occurred approximately 3.5 hours after the pressurized aerosol canister was activated.

Method and Equipment: The hand wipe was conducted using four 4" x 4" 6-ply dressing sponges.

Sampling Procedure(s):

Deposition coupons - Not applicable to this study.

Hand residues- After the 30 minute ventilation period, a test subject entered the room containing the discharged canister, removed the empty canister with their dominant hand, and placed it in a pre-labeled plastic bag and handed it to Toxcon study

personnel. Each subject then picked up the newspaper, which was under the aerosol canister, with their dominant hand, crumpled it using both hands and left the room where they placed the newspaper into a garbage bag. Residues transferred to the hands of the subjects were collected using an isopropyl alcohol based, double wipe method. The hand wipe procedure consisted of wiping the palm of the hand with two 4 inch x 4 inch 6-ply cotton dressing sponges. About 5 mL of IPA was added to each wipe prior to its use. The hand wipe procedure is described in Toxcon SOP M-023 *Collection of a Hand Wipe Sample Following Hand Exposure to Surfaces Treated With a Test Substance*. Each subject's hand wipe samples were placed in separate pre-labeled amber glass jars with teflon-lined lids.

3. Sample Handling and Storage:

The dressing sponges were placed in amber glass jars and stored in the dark at less than -10 C until being shipped to the analytical laboratory. Sample storage and shipment were conducted according to Toxcon Nos. G-022 *Storage of Test Samples and Analytical Extracts* and G-028 *Test Sample Distribution to a Contract Laboratory*. Samples were shipped to the analytical laboratory by airfreight with priority overnight delivery. Samples were shipped in an insulated cooler with dry ice. The samples were received frozen by Xenos Laboratories on July 3, 2002 and stored in a freezer until they were analyzed.

IV. ANALYTICAL METHODOLOGIES

A. Extraction method:

Dressing sponges: Extraction of Pyrethrin I (P-I), Cinerin I (C-I), Jasmolin I (J-I), and PBO residues was performed by sonication and mechanical shaking of the dressing sponge samples at room temperature with ethyl acetate. The extracts were taken to dryness on a rotary evaporator. All sample extracts were made up to a volume of 5.0 mL with acetonitrile. An aliquot of the extract was transferred to an autosampler vial for HPLC/Fluorescece analysis of PBO. Another aliquot of the acetonitrile extract was taken to dryness under nitrogen and reconstituted in toluene. The toluene extract was cleaned up using Isolute silica SPE prior to analysis by gas chromatograph/ electron capture detector (GC/ECD) for the three PYI esters.

B. Detection methods:

A gas chromatograph/ electron capture detector was used for the analysis of PYI and a Shimadzu HPLC system was used for the analysis of PBO. The method measured three Pyrethrin esters (PYI): Pyrethrin I (P-I), Cinerin I (C-I) and Jasmolin I (J-I), and PBO. See Table 1 for specific conditions.

Table 1. Gas Chromatographic / Electron Capture Detector and HPLC Conditions

Gas Chromatographic Conditions	
GC Column	SPB-1, 30 m x 0.32 mm ID, 0.25 μm film
Temperatures	Inlet: Initial - 120°C (hold 0.10 min) Program - 120-280°C @ 20°C/min (hold 10 min) Column: Initial - 90°C (hold 2.0 min) Prog 1 - 90-140°C @ 20°C/min Prog 2 - 140-210°C @ 2.5°C/min Prog 3 - 210-300°C @ 50°C/min (hold 5 or 10 min) Detector: 330°C
Carrier Gas Flow Rate	5.4 mL/min
Injection Volume	2.0 μL (splitless)
Injection Rate	0.5 μL/sec on column
Approximate Retention Times	C-I ~ 26.9 min J-I ~ 29.5 min P-I ~ 30.2 min
Liquid Chromatographic Conditions	
Column	Zorbax Rx-C8, 4.6 x 250 mm
Temperature	30°C
Mobile Phase	Isocratic: 70% acetonitrile 30% water
Flow Rate	1.0 mL/min
Injection Volume	20 μL
Fluorescence Detection	Excitation: 288 nm Emission: 345 nm
Approximate Retention Time	PBO: ~ 9 min

D. Method Validation:

The analytical methods were validated prior to initiation of the field phase of this study to determine the integrity and efficiency of Xenos' modified Analytical Method XAM-66 which was used for the analysis of the three Pyrethrin esters (PYI): Pyrethrin I (P-I), Cinerin I (C-I) and Jasmolin I (J-I) and PBO residues in/on dressing sponge samples. Pyrethrin (PY) was quantitated as the sum of the three PYI esters. The Study Report states that validation data for the limits of quantitation (LOQ) were taken from Xenos report XEN01-12. LOQs are reported for PYI, PY, and PBO (see Table 2).

Table 2. Validated LOQ Values

Matrix	Formulation	PYI	PY	PBO
Dressing Sponges	100 µg	0.440 µg	0.784 µg	1.58 µg

Instrument performance and calibration: The GC/ECD calibration standards were prepared by dilution of the solution containing 5.00 mg of formulation/mL with toluene. A total of five concentrations were used to calibrate the system ranging from 0.005 µg/µL to 0.040 µg/µL. The HPLC/Fluorescence calibration solutions were prepared by dilution of the solution containing 5.00 mg of formulation/mL with acetonitrile. A total of five concentrations were used to calibrate the system ranging from 0.010 µg/µL to 0.080 µg/µL.

E. Quality Control:

Lab Recovery: To obtain recovery and method performance data, concurrent laboratory control dressing sponge samples were fortified with PYI and PBO. Control dressing sponge samples were fortified at the LOQ (0.424 µg/sample for PYI and 1.51 µg/sample for PBO), 5X, 10X, 25X, and 100X the LOQ. Results from the laboratory fortified samples are summarized in Table 3. The percent recoveries ranged from 92.5% to 104% for PYI and from 94.7% to 98.4% for PBO. The overall average recoveries were 98.6 ± 4.7% for PYI and 96.3 ± 1.4% for PBO.

Table 3. Summary of Concurrent Laboratory Fortification Recoveries

Matrix	Fortification Level (µg)		Measured Residue (µg/sample)		Percent Recovery (%)		Overall Average Recovery (%)		Std. Dev.		% RSD	
	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO
Dressing sponge	0.424	1.51	0.436	1.45	103	96.0	98.6	96.3	4.7	1.4	4.76	1.46
			0.396	1.46	93.4	96.7						
			0.442	1.44	104	95.4						
			0.442	1.43	104	94.7						
	2.12	7.55	2.08	7.4	98.1	98.0						
	4.24	15.1	4.12	14.3	97.2	94.7						
	10.6	37.8	10.2	37.2	96.2	98.4						
	42.4	151	39.2	146	92.5	96.7						

Dressing sponge LOQ for PYI = 0.424 µg/sample and the LOQ for PBO = 1.51 µg/sample.
Fortification levels are at 1X, 5X, 10X, 25X, and 100X the LOQ.

Field Fortification: Field fortified dressing sponges were prepared in triplicate by adding approximately 5 mL IPA to each of two dressing sponges and the dressing sponges were transferred to glass jars prior to fortification with the reference substance (containing 0.76% PY and 1.51% PBO as the active ingredients). Each field fortified dressing sponge was treated identically to the study samples. These fortified samples were placed in amber glass jars with teflon-lined lids and stored frozen prior to shipment to the analytical laboratory. Field fortification results are summarized in Table 4. The percent recoveries ranged from 80.9% to 105% for PYI and from 92.4% to 102% for PBO. Overall average recoveries were 95.6 ± 8.38% for PYI and 97.7 ± 3.33% for PBO.

Table 4. Summary of Field Fortification Recoveries.

Matrix	Fortification Level (ug/sample)		Measured Residue (µg/sample)		Percent Recovery (%)		Overall Average Recovery (%)		Std Dev.		%RSD	
	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO	PYI	PBO
Dressing Sponge	2.74	9.75	2.75	9.60	100	98.5	95.6	97.7	8.38	3.33	8.8	3.4
			2.69	9.66	98.2	99.1						
			2.87	9.60	105	98.5						
	27.8	98.8	27.2	101	97.8	102						
			22.5	91.3	80.9	92.4						
			25.4	94.6	91.4	95.7						

Dressing sponge LOQ for PYI = 0.424 µg/sample and the LOQ for PBO = 1.51 µg/sample
Fortification levels are at 6.5X and 65X the LOQ

Control Samples: Four replicate laboratory blank dressing sponge samples and duplicate field blank dressing sponge samples were prepared by adding a volume of solvent approximately equivalent to the volume of solution used in the fortification process. Both the laboratory and field control dressing sponges had detectable PY residue levels that were below the limit of quantitation and there were no detectable levels of PBO.

Storage Stability: The field fortified samples were analyzed after a maximum period of 18 days of frozen storage. The Study Report stated that this confirmed the stability of the residues over this time period. All study samples were analyzed within 18 days of collection.

V. RESULTS

Field fortification recoveries were all >90%; therefore, the data did not need to be corrected. Resides were reported for both PYI and PBO, as well as PY, which is total PY calculated from the PYI data by using a conversion factor (1.7908) derived from the percentages of total PYs and PYI in the formulated product.

A. Alpha Cellulose and Deposition of Formulation:

Not applicable to this study.

B. Hand Residues

Total hand residues transferred from the fogger canister and newspaper to the bare hands were calculated by the study author for each hand of the test subjects. Residues are reported for PYI , PY, and PBO. Residues removed from the hands ranged from 1.37 to 13.6 µg/sample with a mean value of 5.56 µg/sample for PY and ranged from 4.08 to 23.1 µg/sample with a mean value of 9.86 µg/sample for PBO. Versar did not have to correct the data, as all field fortification recoveries were >90%. Versar calculated transfer residue data as $\mu g/cm^2$. Summaries of Versar's calculated total PYI, PY, and PBO transfer residues from both the canister and newspaper are provided in Table 5. Total PY and PBO transfer residues ranged from 0.024 $\mu g/cm^2$ to 0.173 $\mu g/cm^2$ with a mean of 0.074 $\mu g/cm^2$ and from 0.035 $\mu g/cm^2$ to 0.307 $\mu g/cm^2$ with a mean of 0.131 $\mu g/cm^2$, respectively.

The study author also calculated residues transferred from the newspaper to the non-dominant hands as well as residues transferred from the canister and the newspaper to the dominant hands. The dominant hand was initially used to pick up the empty fogger canister, place it in a plastic bag, and then pick up the newspaper off the floor. The

non-dominant hand was then used with the dominant hand to crumble the newspaper and put it in a garbage bag. Therefore, in order to determine the residue transferred from the newspaper to the hand, the residue transferred to the non-dominant hand only was determined, and to determine the residue transferred from the canister and the newspaper to the hand, the residue transferred to the dominant hand only was determined.

The study author reported that the mean PY and PBO residues transferred from the newspaper to the non-dominant bare hands were 43.0 ng/cm^2 and 78.5 ng/cm^2, respectively. The mean PY and PBO residues transferred from the canister and newspaper to the dominant bare hands were 105.1 ng/cm^2 and 184.5 ng/cm^2, respectively. Versar calculated these transfer residue data as µg/cm^2 and summarized them in Table 6. The PY and PBO residues transferred from the newspaper to the non-dominant bare hands ranged from 0.024 µg/cm^2 to 0.068 µg/cm^2 with a mean of 0.043 µg/cm^2 and from 0.035 µg/cm^2 to 0.143 µg/cm^2 with mean of 0.78 µg/cm , respectively. The PY and PBO residues transferred from both the newspaper and the empty canister to the dominant bare hands ranged from 0.027 µg/cm^2 to 0.173 µg/cm^2 with a mean of 0.105 µg/cm^2 and from 0.049 µg/cm^2 to 0.307 µg/cm^2 with a mean of 0.105 µg/cm^2, respectively .

VI. CONCLUSION

Samples analyzed in this study were used to measure the transfer of pyrethrin and piperonyl butoxide from empty fogger canisters and newspapers to bare hands. The study author calculated residues based on the amount removed from the hand by the dressing sponges. Versar did not have to correct the data, as all field fortification recoveries were >90%. The PY and PBO mean residues, as calculated by Versar, transferred to the non-dominant (newspaper only) bare hands were 0.043 ± 0.015 µg/cm^2 and 0.078 ± 0.034 µg/cm^2, respectively. The PY and PBO mean residues transferred to the dominant (newspaper and canister) bare hands were 0.105 ± 0.052 µg/cm^2 and 0.185 ± 0.086 µg/cm^2, respectively.

The dominant hand residue is over twice the non-dominant hand residue. The ratio of PBO to PY on the hand is close to 2, which is the ratio of the compounds in the formulation.

LIMITATIONS OF THE STUDY:

The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study. Overall, the majority of the procedures performed and the quality of the data generated in this study conformed to the criteria set forth in the protocol and guidelines.

- A label was not provided for the test product; therefore, it is unclear whether this rate is appropriate for the intended use.

- None of the test conditions (temperature, barometric pressure, ventilation) were reported.

- According to the Study Report, the fogger canister was placed in a plastic bag and weighed before and after release of its contents to determine the actual amount of formulation that was delivered to the test room taking into account the weight of the bag. However the results from this were not discussed. The actual amount of formulation delivered to the test room was not reported.

Table 5. Summary of Total PYI and PBO Residues Transferred From Canister and Newspaper to Bare Hands

Replicate/Hand	Measured Residue[a] (µg/sample)			Hand Surface Area (cm^2)[b]	Measured Residue[c] (µg/cm^2)			Average Residue (µg/cm^2)		Standard Deviation	
	PYI	PY	PBO		PYI	PY	PBO	PY	PBO	PY	PBO
Subject #1/Left	1.28	2.29	4.12	84.5	0.015	0.027	0.049	0.074	0.131	0.049	0.084
Subject #1/Right	1.68	3.01	5.67	76.2	0.022	0.039	0.074				
Subject #2/Left	1.21	2.17	4.08	91.6	0.013	0.024	0.045				
Subject #2/Right	3.39	6.07	12.3	93.1	0.036	0.065	0.132				
Subject #3/Left	2.37	4.24	8.86	62.1	0.038	0.068	0.143				
Subject #3/Right	6.08	10.9	19.3	62.9	0.097	0.173	0.307				
Subject #4/Left	2.72	4.87	9.28	83.8	0.032	0.058	0.111				
Subject #4/Right	6.87	12.3	20.4	85.7	0.080	0.144	0.238				
Subject #5/Left	0.766	1.37	2.04	57.8	0.013	0.024	0.035				
Subject #5/Right	3.10	5.55	10.5	52.5	0.059	0.106	0.200				
Subject #6/Left	1.82	3.26	5.72	73.0	0.025	0.045	0.078				
Subject #6/Right	2.18	3.90	7.26	72.0	0.030	0.054	0.101				
Subject #7/Left	2.01	3.60	6.35	85.8	0.023	0.042	0.074				
Subject #7/Right	7.57	13.6	23.1	89.8	0.084	0.151	0.257				
Subject #8/Left	1.79	3.21	4.93	72.6	0.025	0.044	0.068				
Subject #8/Right	4.82	8.63	13.8	71.8	0.067	0.120	0.192				

a PY is total PY calculated by using a conversion factor (1.7908) derived from the percentages of total PYs and PYI in the formulated product.

b Based on hand palmer surface area measurements.

c Residue based on hand surface area and converted from µg/sample to µg/cm^2.

Table 6. Summary of PYI and PBO Residues Transferred From Newspaper and Canister to Non-Dominant and Dominant Bare Hands

Replicate/Hand	Measured Residue[a] (µg/sample)			Hand Surface Area (cm^2)[b]	Measured Residue[c] (µg/cm^2)			Average Residue (µg/cm^2)		Standard Deviation	
	PYI	PY	PBO		PYI	PY	PBO	PY	PBO	PY	PBO
Non-Dominant Hand (Newspaper Only)											
Subject #1/Right	1.68	3.01	5.67	76.2	0.022	0.039	0.074	0.043	0.078	0.015	0.034
Subject #2/Left	1.21	2.17	4.08	91.6	0.013	0.024	0.045				
Subject #3/Left	2.37	4.24	8.86	62.1	0.038	0.068	0.143				
Subject #4/Left	2.72	4.87	9.28	83.8	0.032	0.058	0.111				
Subject #5/Left	0.766	1.37	2.04	57.8	0.013	0.024	0.035				
Subject #6/Left	1.82	3.26	5.72	73.0	0.025	0.045	0.078				
Subject #7/Left	2.01	3.60	6.35	85.8	0.023	0.042	0.074				
Subject #8/Left	1.79	3.21	4.93	72.6	0.025	0.044	0.068				
Dominant Hand (Empty Fogger Canister + Newspaper)											
Subject #1/Left	1.28	2.29	4.12	84.5	0.015	0.027	0.049	0.105	0.185	0.052	0.086
Subject #2/Right	3.39	6.07	12.3	93.1	0.036	0.065	0.132				
Subject #3/Right	6.08	10.9	19.3	62.9	0.097	0.173	0.307				
Subject #4/Right	6.87	12.3	20.4	85.7	0.080	0.144	0.238				
Subject #5/Right	3.10	5.55	10.5	52.5	0.059	0.106	0.200				
Subject #6/Right	2.18	3.90	7.26	72.0	0.030	0.054	0.101				
Subject #7/Right	7.57	13.6	23.1	89.8	0.084	0.151	0.257				
Subject #8/Right	4.82	8.63	13.8	71.8	0.067	0.120	0.192				

a PY is total PY calculated by using a conversion factor (1.7908) derived from the percentages of total PYs and PYI in the formulated product.
b Based on hand palmer surface area measurements.
c Residue based on hand surface area and converted from µg/sample to µg/cm^2.

APPENDIX A

Compliance Checklist for "*Determination of Transfer of Pyrethrin (PY) and Piperonyl Butoxide (PBO) Residues to the Hands from a Discharged Indoor Fogger Aerosol Canister and the Paper Placed Under the Aerosol Canister*"

Compliance Checklist for "Determination of Transfer of Pyrethrin (PY) and Piperonyl Butoxide (PBO) Residues to the Hands from a Discharged Indoor Fogger Aerosol Canister and the Paper Placed Under the Aerosol Canister"

GUIDELINE 875.2300
INDOOR SURFACE RESIDUE DISSIPATION
POSTAPPLICATION

1. The test substance must be the typical end use product of the active ingredient. This criterion was possibly met. The test product was said to be a typical total release fogger; however, no label was provided.

2. The production of metabolites, breakdown products, or the presence of contaminants of potential toxicologic concern, should be considered on a case-by-case basis. This criterion does not appear to apply to this study.

3. Indoor surface residue studies should be conducted under ambient conditions similar to those encountered during the intended use season, and should represent reasonable worst case conditions. This criterion was met.

4. Ambient conditions (i.e., temperature, barometric pressure, ventilation) should be monitored. This criterion was mostly met. The target conditions were identified and apparently met, but monitoring data were not provided in the Study Report.

5. The end use product should be applied by the application method recommended on the label. Information that verifies that the application equipment (e.g., sprayer) was properly calibrated should be included. This criterion was met. The Study Report mentioned that according to label directions for the use of indoor foggers the aerosol canister was to be placed on a disposable surface prior to activating.

6. The application rate used in the study should be provided and should be the maximum rate specified on the label. However, monitoring following application at a typical application rate is more appropriate in certain cases. This criterion was not met and may not be applicable to this study. The Study Report did not provide target or actual application rates.

7. If multiple applications are made, the minimum allowable interval between applications should be used. This criterion does not apply to this study. Eight individual runs were performed using one canister per run per room.

8. Indoor surface residue (ISR) data should be collected from several different types of media (e.g., carpeting, hard surface flooring, counter tops, or other relevant materials). This criterion does not apply to this study. The objective was to determine residue transfer to bare hands from contact with empty aerosol fogging canisters and newspaper.

9. Sampling should be sufficient to characterize the dissipation mechanisms of the compound (e.g., three half-lives or 72 hours after application, unless the compound has been found to fully dissipate in less time; for more persistent pesticides, longer sampling periods may be necessary). Sampling intervals may be relatively short in the beginning and lengthen as the study progresses. Background samples should be collected before application of the test substance occurs. This criterion does not apply to this study.

10. Triplicate, randomly collected samples should be collected at each sampling interval for each surface type. This criterion does not apply to this study. Samples were taken of dressing sponges. Eight dressing sponge sample replicates were collected. Since only one group of eight subjects participated in this study, the Study Report stated that no randomization was necessary.

11. Samples should be collected using a suitable methodology (e.g., California Cloth Roller, Polyurethane Roller, Drag Sled, Coupons, Wipe Samples, Hand Press, vacuum cleaners for dust and debris, etc.) for indoor surfaces. This criterion was met. Samples were collected using dressing sponge samples.

12. Surface sampling should be conducted in conjunction with air sampling. Enough duplicate air samples should be taken in a room to establish a dissipation curve. This criterion was not met.

13. Samples should be stored in a manner that will minimize deterioration and loss of analytes between collection and analysis. Information on storage stability should be provided. This criterion was met. Samples were stored in a manner that minimized deterioration and loss of analytes. Dressing sponge field fortification samples were analyzed after a period of 18 days. The Study Report stated that this confirmed the stability of the residues over this time period.

14. Validated analytical methods of sufficient sensitivity are needed. Information on method efficiency (residue recovery), and limit of quantitation (LOQ) should be provided. This criterion was met.

15. Information on recovery samples must be included in the Study Report. A complete set of field recoveries should consist of at least one blank control sample and three or more each of a low-level and high-level fortification. These fortifications should be in the range of anticipated residue levels in the field study. This criterion was met. Blank control samples and field fortification samples were included in the study.

16. Raw residue data must be corrected if appropriate recovery values are less than 90 percent. This criterion does not apply to this study. All average recovery values for PYI and PBO in dressing sponge samples were greater than 90%.

17. Indoor surface residues should be reported as mg per m^2 or cm^2 of surface sampled. Distributional data should be reported, to the extent possible. These criteria were met. Residues from dressing sponge samples were reported as µg/sample and ng/cm^2.

18. Reported residue dissipation data in conjunction with toxicity data should be sufficient to support the determination of a reentry interval. This criterion does not apply to this study.